UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

JESSICA ANTONACCI,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 4:20-CV-001841 AGF
	)	
ALLERGAN USA, INC., et al.,	)	
	)	
	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter is before the Court on the motion to dismiss of two of the four Defendants in this case, Allergan USA, Inc. and Allergan Inc. (collectively "Allergan Defendants"). The other Defendants are AbbVie, Inc. and Allergan Limited. The Allergan Defendants move to dismiss Plaintiff's complaint pursuant to Fed. R. Civ. P. 12(b)(6). Plaintiff originally filed this case in state court asserting claims arising from a ruptured breast implant. Defendants removed the case on December 21, 2020 on the basis of diversity jurisdiction. (Doc. No. 1). The Allergan Defendants argue Plaintiff's claims are expressly preempted by 21 U.S.C. § 360k(a).[1] Section 360k(a) preempts state regulations of medical devices that are "different from, or in addition to, any requirement" made applicable through the Food and Drug Administration ("FDA"). 21

[1] Defendants AbbVie, Inc. and Allergan Limited filed a separate to dismiss for lack of personal jurisdiction and insufficient service of process. The Court will consider their motion separately.

U.S.C. § 360k(a). Plaintiff argues preemption violates her right of access to the courts as protected by the Privileges and Immunities Clause. U.S. Const. art. IV, § 2, cl. 1. For the reasons set forth below, Plaintiff's claims against these two Defendants will be dismissed.

BACKGROUND

On September 2, 2008, Plaintiff underwent breast augmentation surgery and was implanted with a set of Natrelle style silicone breast implants designed by Allergan USA, Inc. and Allergan Inc. (Doc. No. 1-1 at ¶ 2). The Natrelle style breast implants received premarket approval ("PMA") from the FDA.[2] Approximately ten years later, Plaintiff noted the left implant appeared deformed. On January 29, 2019, she had surgery to replace her implants. *Id*. at ¶¶ 4-5. Plaintiff's left breast implant had ruptured and was leaking. *Id*. at ¶ 6. In July 2019, the implants in question were the subject of a recall by the FDA. On November 17, 2020, Plaintiff filed this suit in state court asserting claims of failure to warn (Count I), negligence (Count II), breach of the implied warranty of merchantability (Count III), and violation of the Missouri Merchandising Practices Act (Count IV). Defendants removed the case to federal court based on diversity jurisdiction. AbbVie and Allergan Limited moved separately to dismiss for lack of personal

[2] The Court may take judicial notice of public records and consider them on a motion to dismiss. *See Stahl v. U.S. Dept. of Agric.*, 327 F.3d 697, 700. "Matters of public record may include records and reports of administrative bodies." *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 984 n.1 (E.D. Mo. 2014) (taking judicial notice of a PMA). The Court will take judicial notice of the Natrelle style breast implants' PMA. *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020056 (last accessed April 8, 2021) (FDA's original PMA approval listing); https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020056S026 (last accessed April 8, 2021) (supplemental approval). Moreover, Plaintiff does not contest that the Natrelle style breast implants received a PMA.

jurisdiction and improper service of process. The Allergan Defendants move to dismiss the case under Fed. R. Civ. P. 12(b)(6).

DISCUSSION

"To survive a 12(b)(6) motion to dismiss, 'a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *McShane Constr. Co. v. Gotham Ins. Co.*, 867 F.3d 923, 927 (8th Cir. 2017) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). The purpose of a motion to dismiss is to test the legal sufficiency of the complaint. The factual allegations of a complaint are assumed true and construed in favor of the plaintiff "even if it strikes a savvy judge that actual proof of those facts is improbable." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) (citing *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 508 (2002)). But "[c]ourts are not bound to accept as true a legal conclusion couched as a factual allegation, and factual allegations must be enough to raise a right to relief above the speculative level." *Torti v. Hoag*, 868 F.3d 666, 671 (8th Cir. 2017) (internal quotation omitted).

In 1976, Congress passed the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA"). *See* 21 U.S.C. § 360c *et seq*. The amendments authorized the FDA to "regulate the safety and effectiveness of medical devices." *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1203 (8th Cir. 2010).

The MDA expressly preempts certain state laws. Subject to some unrelated exceptions:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The United States Supreme Court has articulated a two-part test for applying the express preemption principles codified in Section 360k of the MDA. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321–22, 128 S. Ct. 999, 1007 (2008). The test requires the court to examine the particular federal laws and regulations applicable to the device in question and compare them to the state claims the plaintiff wishes to bring. First, the court must determine whether "the Federal Government has established requirements" applicable to a particular device. Second, the court must determine whether a plaintiff's claims "are based upon [state] requirements with respect to the device that are different from, or in addition to the federal ones, and that relate to safety and effectiveness." *Id.* If the court answers both questions in the affirmative, the state laws are expressly preempted by the MDA. *Id*. However, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330. Premarket approval is a federal "requirement" that meets the first prong of the test for Section 360k preemption. *Id*. at 322-23. (PMA was "specific to individual devices" and "focused on safety, not equivalence."). As for the second prong of the Section 360k preemption test, included in the meaning of "state requirements"

subject to federal preemption are common law causes of action, such as negligence and strict liability. *Id.* at 323-244.

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S. Ct. 1012, 148 L.Ed.2d 854 (2001), the Supreme Court construed § 337(a) of the MDA—which provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." The Supreme Court determined § 337(a) bars "suits by private litigants 'for noncompliance with the medical device provisions.'" *In re Medtronic*, 623 F.3d at 1204 (quoting *Buckman*, 531 U.S. at 349 n.4, 121 S. Ct. 1012). The Eighth Circuit has read *Buckman* and *Riegel* together to create a "narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Id.* (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). As such, a plaintiff "must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic*, 623 F.3d at 1204 (quoting *Riley*, 625 F. Supp. 2d at 777) (emphasis in original).

I. Plaintiff's Claims are Preempted

In response to Defendants' assertion that her claims are preempted by § 360k(a), Plaintiff states without elaboration, "There was an obvious failure by Defendant Allergan that caused Plaintiff's breast augmentation to rupture while in her body. Plaintiff challenges 21 U.S.C. § 360c *et seq*. and the Federal preemption of Plaintiff's claim based upon product liability of her breast augmentation." (Doc. No. 33 at 3). Finding no

illumination in this statement, the Court will simply apply the two-step test from *Riegel* and evaluate the claim pursuant to *Buckman*.[3] First, the Court must consider whether the government established requirements applicable to the medical device at issue. Premarket approval is a federal "requirement" that meets the first prong of the test for § 360k preemption and the Natrelle style breast implants at issue in this case have a PMA.[4]

Second, the Court must determine whether the state law claims Plaintiff raises impose requirements that are "different from, or in addition to," federal requirements. *Riegel*, 552 U.S. at 321. "Absent concrete allegations that the product sold by [Defendant] was not the product design approved in the PMA Supplement, these are not parallel claims. Rather, they are attacks on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device. Such claims are expressly preempted by § 360k." *In re Medtronic, Inc.*, 623 F.3d at 1206. Plaintiff's claims may also be preempted pursuant to *Buckman* if the claim alleges Defendants failed to comply with the FDA.

Failure to Warn and Negligence

Plaintiff's claims for failure to warn and negligence are both premised on the same underlying conduct, so the Court will address them together. Plaintiff alleges:

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[3] *Riegel* and *Buckman* preempt claims even if the medical device at issue is subject to a recall. *See In re Medtronic*, 623 F.3d at 1205 n.4.

[4] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020056 (last accessed April 8, 2021) (PMA approval listing for the Natrelle style implants).

> Defendant Allergan[5] knew, or should have known in the exercise of ordinary care, that the Natrelle style breast implants were unreasonably dangerous at the time the implants left Defendant Allergan's control and were received by Plaintiff, and their unreasonably dangerous nature was not generally known to the consumer. Defendant Allergan acquired this knowledge from the performance of extensive studies, reviewing other scientific studies, complaints received from consumers, as well as other sources. Further, the Natrelle style breast implants' health risks were known in the scientific and medical community at the time of their manufacture, distribution, or sale.

(Doc. No. 1-1 at ¶ 20).

In both her failure to warn and negligence claims, Plaintiff asserts that the Allergan Defendants failed to warn her of the higher risks associated with the Natrelle style breast implants or submit adverse event reports to the FDA. Plaintiff does not claim the implants she received were faulty or failed to comply with the PMA design; instead, she claims the Natrelle style breast implants were unreasonably dangerous as designed and the Allergan Defendants did not warn her of the increased risk.

The allegation that "by reason of state law, [Defendants were] required to give additional warnings" is "precisely the type of state requirement that is 'different from or in addition to' the federal requirement and therefore preempted." *In re Medtronic, Inc.*, 623 F.3d at 1205 (citing *Riegel*, 552 U.S. at 330). Moreover, "common-law causes of action for negligence and strict liability impose requirements and would be pre-empted by federal requirements specific to a medical device." *Riegel*, 552 U.S. 312, 323–24, 128 S. Ct. 999, 1007, 169 L. Ed. 2d 892 (2008) (internal quotations omitted). Accordingly,

[5] Plaintiff refers to all four Defendants collectively as "Allergan." (Doc. No. 1-1 at ¶ 12).

insofar as Plaintiff's claims allege the implants were unreasonably dangerous or that the Allergan Defendants failed to give her adequate warnings, her claims are preempted under *Riegel*.

Plaintiff further contends that Defendants failed to provide reports on the safety of the implants, failed to comply with FDA reporting requirements, and intentionally concealed the risks associated with the implants. (Doc. No. 1-1 at ¶¶ 21-22, 32-33). An allegation that a defendant "failed to provide the FDA with sufficient information and did not timely file adverse event reports" is "simply an attempt by private parties to enforce the MDA" and is therefore preempted pursuant to *Buckman*. *In re Medtronic, Inc.*, 623 F.3d at 1205–06. *See also Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 989 (E.D. Mo. 2014) ("even if plaintiff based this claim on Medtronic's failure to file an adverse event report with the FDA, the Eighth Circuit has held that such a claim is preempted under *Buckman*."). The Court concludes that insofar as Plaintiff bases her failure to warn or negligence claims on the Allergan Defendants' alleged violation of FDA reporting requirements, her claim is preempted pursuant to *Buckman*. Because Plaintiff does not allege any conduct that falls within the narrow gap between *Riegel* and *Buckman*, Plaintiff's claims for failure to warn and negligence must be dismissed.

Implied Warranty of Merchantability

Plaintiff claims the Allergan Defendants breached the implied warranty of merchantability because the implants contained hidden flaws—the increased risk of rupturing caused by the Natrelle style breast implants. (Doc. No. 1-1. at ¶ 46-7). Claims that a medical device presents "an unreasonably dangerous risk beyond what the ordinary

consumer would reasonably expect" are preempted by § 360k. *In re Medtronic, Inc.*, 623 F.3d at 1205. *See also Williams v. Bayer Corp.* 541 S.W.3d 594, 601 (Mo. Ct. App. 2017) (finding a claim for implied warranty of merchantability preempted by the MDA). Because Plaintiff's claim alleges that the Natrelle style breast implants are unreasonably dangerous it is preempted pursuant to *Riegel*.

Missouri Merchandising Practices Act

Plaintiff contends Defendants violated the Missouri Merchandising Practices Act ("MMPA") because they "concealed the true risks of the Natrelle style breast implants." (Doc. No. 1-1 at ¶ 56). "[A] finding that the statements" made by defendants "were false or deceptive in violation of the MMPA would be fundamentally equivalent to finding that the FDA's approved labeling was false or deceptive." *Williams*, 541 S.W.3d at 602–03 (MMPA claim alleging promotional statements on a website are misleading is preempted). Plaintiff's allegations that the Allergan Defendants failed to warn her of the true risks of the Natrelle style breast implants would require a finding that the FDA's approved labelling was inadequate because it did not contain a sufficient warning. This claim, much like Plaintiff's other claims, essentially alleges the Allergan Defendants failed to provide warnings outside those required by the FDA and is therefore preempted. *See In re Medtronic, Inc.*, 623 F.3d at 1205.

II. Preemption Does Not Violate the Privileges and Immunities Clause

Plaintiff contends that Federal preemption violates her right of access to the courts, as protected by the "Privileges and Immunities" clause of the Constitution found at

Article IV, Section II, Clause I. (Doc. No. 33 at 3). Plaintiff provides no further analysis supporting this argument.

The Privileges and Immunities Clause applies to the actions of the States, not of Congress. It states: "The Citizens of each State shall be entitled to all Privileges and Immunities of Citizens in the several States." U.S. Const. art. IV, § 2, cl. 1. "The primary purpose of this clause, like the clauses between which it is located—those relating to full faith and credit and to interstate extradition of fugitives from justice—was to…insure to a citizen of State A who ventures into State B the same privileges which the citizens of State B enjoy." *Toomer v. Witsell*, 334 U.S. 385, 395, 68 S. Ct. 1156, 1162, 92 L. Ed. 1460 (1948). *See also Hicklin v. Orbeck* 437 U.S. 518, 523–24, 98 S. Ct. 2482, 2486, 57 L. Ed. 2d 397 (1978) (The Privileges and Immunities Clause "establishes a norm of comity that is to prevail among the States with respect to their treatment of each other's residents.") (internal citations and quotations omitted). The Privileges and Immunities Clause requires *states* to treat the residents of other *states* equally—it does not bar Congress from preempting the judiciary from hearing certain cases. The Privileges and Immunities Clause is unrelated to preemption under § 360k(a).

Furthermore, congressional preemption of state law claims is not unconstitutional. The Supreme Court has long recognized the power of Congress to limit cases the courts may hear. *See Walker v. United States*, 71 U.S. 163, 165, 18 L. Ed. 319 (1866) ("This court has no appellate jurisdiction, except such as is defined by Congress."); *Eng. v. Gen. Elec. Co.*, 496 U.S. 72, 78, 110 S. Ct. 2270, 2275, 110 L. Ed. 2d 65 (1990) ("Congress can define explicitly the extent to which its enactments pre-empt state law."). "The lower

federal courts are all courts of limited jurisdiction, that is, with only the jurisdiction which Congress has prescribed." *Chicot Cnty. Drainage Dist. V. Baxter State Bank*, 308 U.S. 371, 376, 60 S. Ct. 317, 84 L. Ed. 329 (1940). Congress has determined that claims such as Plaintiff's are preempted. Accordingly, this Court cannot hear her claims.

CONCLUSION

The Court finds Plaintiff's state-law claims are either expressly or impliedly preempted by the MDA because they either seek to impose new requirements on the Natrelle style breast implants or impermissibly attempt to enforce the MDA.

Accordingly,

IT IS HEREBY ORDERED that Defendants Allergan USA, Inc. and Allergan, Inc.'s Motion to Dismiss is **granted**. (Doc. No. 22).

AUDREY G. FLEISSIG
UNITED STATES DISTRICT JUDGE

Dated this 4th day of August, 2021.